



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 18, 2013

The Honorable Mike Quigley
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Quigley:

Thank you for your letter regarding the Department of Health and Human Services' (HHS) evaluation of the current blood donation deferral criteria for men who have sex with men (MSM). The Department has committed to a review of the current blood donation deferral criteria for MSM. We are committed to maintaining a safe and available blood supply and appreciate your support on this issue.

As you know, following the recommendation of the Advisory Committee on Blood Safety and Availability, Dr. Howard Koh, Assistant Secretary for Health, charged a Department-wide working group of senior-level scientists to explore the feasibility for a data- and science-driven policy change to the current donor deferral for MSM. The working group developed and supported the implementation of three new research studies and one new operational assessment to help inform a potential policy change. Additionally, the working group developed options for a possible pilot operational study of revised donor eligibility criteria for MSM.

The Department released a Request for Information soliciting public input on the design and feasibility of a possible pilot operational study to investigate the safety of blood donation by MSM under revised donor eligibility criteria. A working group of senior level scientists at the Department reviewed and evaluated the responses based on the following considerations: specific parameters to distinguish between high- and low-risk MSM, duration of abstinence for MSM prior to blood donation, elements of a proposed operational study, weight of data from existing studies, scientific rigor, outcome measures, and other factors. We received 11 responses, with no clear consensus regarding a study framework or the considerations that should guide a change in policy. Only one response proposed an actual study, but the working group determined that it would be impractical due to its large study size, high cost, and the length of time needed to bring it to completion. Members of the working group considered other pilot operational studies that might provide the type of meaningful results that could inform policy change. However, after considerable deliberation, the HHS scientists concluded that all of the proposed operational studies would take several years to complete, cost many millions of dollars, and would likely fail to achieve participation rates necessary for sufficient statistical strength to produce the level of data required to adequately inform a change in donor deferral policy for MSM. The working group determined that the Department's resources could be used in more

effective ways to complete its review of the blood donation deferral criteria and to more quickly reach an appropriately-informed decision on this policy.

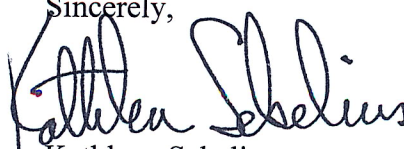
In July of this year, the working group briefed Dr. Koh and other senior leaders in the Department; there was no written report produced for this meeting. At the conclusion of this meeting, the assembled leaders agreed that prior to any change in current blood donor deferral policy for MSM, studies underway (see below) should be completed and analyzed, and that it would be necessary to enhance blood donor and recipient surveillance to monitor transmissible diseases and to ensure the ongoing safety of the blood supply.

At the briefing, the working group summarized the expected timelines for the three ongoing studies and the one operational assessment. As you know, two of these studies and the operational assessment are planned for completion in 2013: a report from the Quarantine Release Error (QRE) Task Force will include a root cause analysis of QREs at blood collection centers and address methods for minimizing the risk of units of blood that test positive for viral markers being released into the blood supply; the Centers for Disease Control and Prevention's National Center for Health Statistics validation study of the Uniform Donor History Questionnaire will provide data on a cognitive evaluation of whether or not the donor questionnaire accurately assesses high risk sexual behavior; and the National Institutes of Health (NIH) Retrovirus Epidemiology Donor Study-II (REDS-II) will provide baseline data on the risk of blood transmissible diseases in relation to behavior risk factors in donors. In 2014, NIH's REDS-III study will provide data on the donation attitudes and behaviors of MSM who would likely donate under a policy change.

HHS is monitoring the policies of countries that changed their MSM donor deferral periods, and we are reviewing the data from other countries regarding their MSM blood donor policies in order to better inform our own deliberations. We look forward to reviewing these prospective data as they become available.

Absent any unexpected delays in the completion or analyses of the studies, we anticipate finishing our internal deliberations on a policy recommendation by late 2014. We are also actively exploring options for enhancing blood donor and recipient surveillance to monitor transmissible diseases prior to any potential policy change.

I appreciate your support and attention to this important issue as the Department continues its work to ensure the safety of the nation's blood supply. I will also provide this response to the cosigners of your letter.

Sincerely,

Kathleen Sebelius